

### REMARKS

Claims 1-34 are pending in this application. In the Non-Final Office Action dated February 27, 2006, all of the claims were rejected. In particular, claims 1-4, 7-13, and 16-20 were rejected under 35 USC §102(b) over U.S. 5,224,185 to Giesy et al (Giesy). Claim 34 was rejected under 35 USC §102(e) over U.S. 6,960,160 to Browning (Browning). Claims 5-6 and 14-15 were rejected under 35 USC §103(a) over Giesy. Claims 10 and 19-33 were rejected under 35 USC §103(a) over Browning in view of U.S. 5,324,306 to Makower et al (Makower).

Applicants cancel claim 34 without prejudice. Applicants amend claims 1, 20, 27, 28, 29, and 32 to correct matters of form. All amendments are supported in the specification and figures, and no new matter is added.

#### Claims 1-20 distinguish over Giesy

The Action rejects claims 1-20 over Giesy. Claim 1 is directed to a delivery device for delivering an implant to an anatomical location comprising a handle, a shaft, a pusher tube, and a pushing mechanism for actuating the pusher tube distally to deliver an implant to the anatomical site. More particularly, claim 1 in part recites:

“a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along a portion of the shaft to deliver an implant to an anatomical site.”

The Action asserts that Giesy describes a device 10, including a handle 12, a needle 20, a flexible sheath 22, and a thumb piece 24, wherein the thumb piece 24 is for actuating the flexible sheath 22 distally to deliver an implant 40 to an anatomical site. Applicants disagree. The thumb piece 24 is not for actuating the flexible sheath 22 distally to deliver an implant 40. In fact, the thumb piece 24 in Giesy is actually for actuating the sheath 22 distally to lockingly engage the implant to the delivery device, instead of delivering it. More particularly, columns 6-7 of Giesy state:

“once the loop 44 is positioned and retained within the indentation 46, the distal end 22b of sheath 22 may be advanced by movement of thumb piece 24 (FIG. 2), beyond the distal end 20b of needle 20. In such configuration, the loop 44 is drawn into sheath 22 and lockingly engaged with indentation 46.”

Thus, Applicants request reconsideration and withdrawal of the rejection over Giesy of claim 1. Similarly, independent claim 10 recites “a pushing mechanism ... for actuating the pusher tube distally along a portion of the shaft to deliver the implant to the anatomical site.” Accordingly Applicants request withdrawal of the rejection over Giesy of this claim. Claims 2-9 and 11-20 depend from these independent claims and add features thereto. Therefore, Applicants request withdrawal of the rejections over Giesy of all of these claims.

Browning is not valid prior art for at least claims 10 and 19

The Action in part relies on Browning in its rejections of claims 10 and 19. Claim 10 relates to a system for delivering an implant comprising an implant, and a delivery device including a handle, a shaft, a pusher tube, and a pushing mechanism. Claim 19 relates to the system of claim 10, wherein the implant comprises a sling assembly. Applicants submit that claims 10 and 19 are supported by prior applications 60/286863 (filed 4/6/2001) and 60/274843 (filed 3/9/2001). The Examiner addresses “guide tubes” in point 2 of the Action to assert that claim 19 is not entitled to the benefit of these prior applications. However, Applicants note that neither claim 10 nor claim 19 recite features related to guide tubes. Therefore, Browning, whose international filing date is, as far as Applicants are aware, October 12, 2001, does not qualify as prior art under 35 U.S.C. §102 or §103 for these claims. Applicants respectfully request withdrawal of the 35 USC §103(a) rejections of these claims over Browning.

Browning/Makower is an improper combination for rejecting claims 20-33

According to MPEP 2142:

- “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.”
- “The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of

reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."

The cited references do not explicitly or implicitly suggest modifying or combining their teachings to produce the system of amended claim 10, nor has the Examiner presented any evidence of why one of ordinary skill in the art would have been so motivated. Makower does not suggest the use of a pushing mechanism for delivering a sling assembly to an anatomical site, and in fact does not suggest the desirability of any sling assembly. Moreover, Browning does not suggest the desirability of any pushing mechanism at all. In fact, the soft tissue anchor 30, cited by the Examiner as a guide tube, includes winged sections 34 which "prevents retraction of the soft tissue anchor 30 from the soft tissue" and "once the soft tissue anchor has penetrated the rectus sheath fascia 120 ... the introducing tool 50 can be withdrawn ... leaving the soft tissue anchor 30 in place" (column 9 lines 40-47). Thus, a pushing mechanism is not needed or desirable with the tool 50 in order to disassociate the introducing tool 50 and the implant 20, since the winged sections 34 leave the soft tissue anchor 30 implanted in soft tissue when the introducing tool 50 is withdrawn. Thus, one of ordinary skill in the art would not be motivated to apply the pusher mechanism to the introducing tool 50.

In view of the foregoing, Applicants request reconsideration and withdrawal of the §103(a) rejections of claims 20-33.

Claims 25-33 further distinguish over Browning in view of Makower

Notwithstanding that Browning/Makower is an improper combination as discussed above, Applicants also submit that independent claims 25 and 32 distinguish over Browning in view of Makower. Claim 25 is directed to a method of delivering a sling into the body of a patient in which a guide tube is slid off of a shaft using, for example, a pusher mechanism. More particularly, amended claim 25 in part recites:

"slideably interfitting a first guide tube attached to a first end of a sling over a distal end and along at least a portion of a length of a shaft,  
positioning at least the distal end of the shaft in a body of a patient,  
sliding the first guide tube off the shaft to deliver a first portion of the sling into the body of the patient"

The Action asserts that Browning describes sliding a first guide tube off a shaft to deliver a first portion of the implant at Figure 8. Applicants disagree. More particularly, the cited

passage relates to a method for placing a soft tissue anchor 30, which the Examiner takes as a guidetube, and states that "the introducing tool 50 can be withdrawn, as shown in FIG. 8C, leaving the soft tissue anchor 30 in place." Thus, even if the soft tissue anchor 30 can be read as a guidetube, the cited portion only describes sliding a shaft from a stationary guidetube, as opposed to sliding a guide tube off a shaft. Makower does not cure the deficiency of Browning at least because the Makower does not describe guide tubes at all.

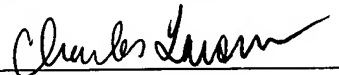
Similarly, independent claim 32 recites "sliding the first guide tube off the first shaft to deliver a first portion of the implant into the body of the patient," and claims 26-33 depend from these claims and add further features thereto. Therefore, Applicants request reconsideration and withdrawal of the §103(a) rejections to these claims.

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P01-024 from which the undersigned is authorized to draw.

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Respectfully submitted,

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